NOTICE

The document below was developed by the NHRPAC workgroup on financial relationships for review and comment by NHRPAC at it's April 9th - 10th meeting. It was drafted in a format so that upon approval by the entire NHRPAC committee it could be forwarded by NHRPAC's chair to OHRP, the Assistant Secretary for Health and the Secretary. Please note that at this point in time this is a DRAFT document, which will be further revised by the working group based on the discussion that took place at the April 9th– 10th meeting. Once those changes are incorporated, the document will be resubmitted to NHRPAC for review and comment at the July 30th– 31st meeting. Therefore, to date, there is no final document approved by NHRPAC.

If you would like to submit comments on this document, please do so by writing to:

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TO: Mary Faith Marshall, Ph.D, Chair and NHRPAC COMMITTEE MEMBERS

FROM: Mark Barnes, J.D., Chair and Members of the
Financial Relationships Workgroup

DATE: April 9, 2001

The National Human Research Protections Advisory Committee (NHRPAC) has, as part of its charter, the responsibility and duty of advising the Department and the Director of the Office of Human Research Protections (OHRP) on significant issues in the regulation and oversight of human subjects research. NHRPAC's particular duty is to advise on issues that relate directly to the welfare and safety afforded those patients who agree to participate in human subjects research. As part of that mission, NHRPAC has undertaken over the past two months, through a convened Working Group and through discussions and deliberations at its plenary meetings, to examine the current status of Department regulation and oversight of conflicts of interest — primarily but not only financial conflicts of interest — that can occur in human subjects research. These conflicts of interest may relate to investigators, other research staff, IRB members, and institutions or entities themselves at which research is conducted or where the research process is monitored or overseen.

As you know, in August 2000, the Department held a public conference on Human Subjects Protection and Financial Conflict of Interest. The conference's deliberations made it clear that there are in fact multiple gaps in the Department's regulation and oversight, and in institutional regulation and oversight, of financial conflicts of interest. Most recently, the Department issued a document for public comment on this issue, *Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators and IRBs To Consider When Dealing with Issues of Financial Interests and Human Subject Protection*. Since this document has attempted to recapitulate the issues and positions that seemed to prevail at the August 2000 conference, and since the document is an actual proposed step that the Department may take regarding guidance on these issues, NHRPAC therefore has

focused on examining this document and commenting on the issues and positions set forth in it.

First Principles and Assumptions

NHRPAC recommends that in order to place these issues in context, the Department — like any entity seeking to issue guidance in this area — set forth clearly its goals and assumptions. For NHRPAC, for example, the goals are to protect human subjects and to allow them to make informed decisions — in many cases, altruistic decisions — to participate in human subjects research; to encourage human subjects research for the broad goal of advancing medical science and public health practice; and to safeguard the integrity of research data, analysis and interpretation. The implied threat of a financial conflict of interest held by any party participating in research is that such a conflict could provide incentives for that party to compromise communications to patients, decisions, judgments, or reports at any point (or at multiple points) in the research process, in order to serve that financial interest, when and if the financial interest conflicts with the values of truth and integrity.

Data to substantiate a correlation of remuneration with inappropriate professional judgment appear, at the present time, limited, although a meta-analysis of 29 studies published in JAMA in January 2000 indicated that financial remuneration and benefits flowing from vendors significantly influenced physician prescription patterns[1]; and yet physician prescriptions to patients should be, in a moral universe, impelled only by the patient's best interests. The corollary in human subjects research would be that the promise of money or stock interest, or

[1] Wazana, Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?, 283 J.A.M.A. 373 (Jan. 19, 2000).

both, could or would distort investigators'[2] and other parties' judgments, actions, and communications to patients. In human subjects research, of course, the many parties, including researchers, should properly be driven by the moral objective of performing responsible research and thus promoting medical science for the general interests of all patients, even while keeping research subjects informed and protecting the subjects' own safety and welfare. These moral goods are advanced through solid research technique, accurate reporting, and prudent, scientific interpretation of data.

The exciting causes of current attention to these issues are not, however, hypothetical assumptions from certain studies, but instead relate to various recent anecdotal reports of alleged research misconduct in which financial interests of researchers and/or institutions may have contributed to compromises of research subject safety, informed consent, and/or research integrity. Some argue forcefully that the long-range self-interest of researchers, institutions, and

sponsors dictate that these conflicts, if and when they exist, would not necessarily lead to adulteration of subject safety and/or the integrity of data or interpretation, since actual fault in this regard would ultimately undermine results, reputations, product value, and thus, eventually but inexorably, product profits. At the same time, one might assume that risks of untoward influence of financial interest on professional integrity might be higher among enterprises, entities or professionals whose reputations, profits or stock prices rise or fall entirely on the basis of a single novel medical device, drug or biotechnology agent.

These issues are currently beyond NHRPAC's, and presumably the Department's, ability to resolve definitively. Yet many public health and medical ethics issues require action in the face of data that is neither entirely confirmatory nor definitive. In such cases, action is normally taken in considered, step-wise fashion, with evaluation at each turn, and consideration of data as they become available. In current circumstances, with biotechnology, medical device and drug research proliferating (which is, NHRPAC believes, a decided good); with financial interests held by researchers and institutions increasingly common, at least according to multiple anecdotal reports; and with multiple adverse research events involving questionable investigator and/or institutional judgment having been reported as also involving questionable financial relationships; the Department should recognize that taking precautionary measures to protect research subjects and research integrity is now indicated. In NHRPAC's view, while the exact parameters, details, and process of Department guidance should be open to debate, the need for the Department to act in a careful and prudent way on these issues should not, at this point, be doubted. In fact, not to act in these circumstances itself could undermine public confidence in

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[2] In this document, the terms "researchers" and "investigators" are used interchangeably, and include, for all purposes of this letter, research staff exercising independent judgment over data gathering, monitoring, analysis and interpretation, and those involved in the informed consent process with research subjects.

the overall enterprise of human subjects research, thus foiling the achievement of a primary goal of responsible regulation, which is to encourage research as a social good.

NHRPAC notes that many of the recent comments received on the *Draft Interim Guidance* dispute the need for the issuance of the guidance, contest the form of the guidance itself, and assert that any additional Departmental guidelines or regulations should await the outcome of processes now in motion by which various associations or entities seek to craft their own "best practices" guidelines. NHRPAC takes issue with these points. First, understanding the insufficiency of data on these issues and yet the compelling need to assure the welfare of research subjects and research integrity, NHRPAC regards it as entirely appropriate for the Department to act forthwith in a careful, limited fashion, with provision made for periodic review and revamping of guidelines, as practice informs. The issuance of non-regulatory, suggested "best practices" guidance through an interim guidance document does not seem, depending of course on that document's ultimate content, inconsistent with the goal of prudent governmental action on a rapidly evolving issue.

Some professional organizations — in particular the American Society of Gene Therapy, which has simply forbidden its researcher members from ownership interest in products they are testing — already have guidelines in place, as do multiple institutions. The complications inherent in the issue have not prevented financial conflicts of interest policies from being adopted for purposes of research and also for purposes of general physician, medical staff, hospital and industry compliance. These considerations have led NHRPAC to the conclusion that meaningful government action on the issue should proceed, and should not be postponed until after any one or more private organizations have themselves acted. Private associations and entities, however, should be encouraged to submit meaningful comments on proposed Departmental guidance and should be encouraged to participate as the guidance is evaluated and refined. As final private guidelines are adopted, the Department could consider, as appropriate, integrating valuable features of those privately developed guidelines into the federal guidance documents or regulations.

NHRPAC would encourage the Department to solicit from private associations, entities, researchers, and patient representatives case studies of conflicts of interest and how those conflicts might appropriately be handled or managed. These illustrative examples, based on actual experiences of those engaged in the research endeavor, could be offered for all of the major points of guidance, and could help to clarify responsible individual and institutional behavior in this area.

Finally, as a general comment on the *Draft Interim Guidance*, NHRPAC strongly encourages the Department to review all precatory language in the draft, so that distinctions may be accurately and consistently made between "must" (conveying a legal duty), "should" (conveying a moral duty), and "may" or "might" (conveying a suggestion of one non-exclusive possibility of legally or morally appropriate behavior). As it is, the document could profit from clarification of its injunctions and suggestions by deliberate, consistent use of these terms.

Defining "Relevant Financial Relationships" and "Conflicts of Interest"

NHRPAC encourages the Department to be careful in distinguishing between a duty to disclose or a process of disclosure of financial interests, on the one hand, and identification of a financial interest as a conflict of interest, on the other. In many cases in the draft document and in the course of the meeting in August 2000, the term "conflict of interest" has been used, for example, to signify the presence of any financial interest. This has seemed to NHRPAC an inappropriate, inexact and overly broad use of the term, since mere presence of a financial investment or relationship that is disclosed does not necessarily result in a meaningful or significant conflict of interest that must be managed. At the same time, although the draft document's approach seems to emphasize a "financial relationships" approach, this does not fully

capture what is at the core of the moral and legal concerns, which is that some financial relationships in research may be so significant as to present a true conflict of moral and legal duties among researchers and institutions. The term "financial relationship" is thus not entirely accurate in describing the issue that has recently caused much consternation among the research community and the regulatory authorities. Some financial relationships are so trivial or so attenuated that they cannot be thought of as posing any significant risk of "conflict of interest." Similarly, moral and regulatory scrutiny is required, for all the reasons set forth above, not for any and all "financial relationships," but only for those that pose some significant risk of conflict of interest. Perhaps what is called for here is a third category, falling between mere "financial relationships" and well established "conflicts of interest" — that is, a category of financial relationships that would appear directly related to the research but which cannot definitively be classified as "conflicts of interest." Terms to describe this category might include "complicating financial relationships," "troubling financial relationships," or even "relevant financial relationships."

Suggested financial disclosure policies for IRB members, investigators, and institutions should contemplate, at the outset, strict confidentiality protections for the information disclosed, in order to protect the privacy interests of researchers; lack of confidentiality will only serve as a disincentive for researchers to disclose, especially in "close" cases in which their financial interests' relation to the research is attenuated or unclear (for example, if they own significant financial interests in a company offering a product that competes or would compete with the product under investigation). That true conflicting or troubling financial interests may ultimately be disclosed to patients on a case-by-case basis (as is contemplated below in these comments) does not at all militate against strict privacy for the process of disclosure to a conflict of interest committee and the IRB in the conflict of interest process, since many interests disclosed may be judged not to represent conflicts of interest.

Disclosure policies also should include some threshold amount below which a financial interest (*e.g.*, investments, stock holdings, honoraria, paid travel expenses) is so minute or attenuated that it cannot be said to constitute a conflict of interest, or even a "complicating financial relationship." Although an interest of, for example, $5000 might represent a large sum with large meaning for a particular investigator, in general, existing policies for the Public Health Service (PHS) and the Food and Drug Administration (FDA) allow *de minimis* exceptions to their disclosure requirements, just as certain fraud and abuse statutes and regulations also allow such exceptions to general prohibitions. NHRPAC noted in its deliberations that increasingly, institutions at which research is conducted have adopted the PHS standard of a $10,000 interest or 5 percent ownership in an enterprise that would "reasonably appear to be affected by the

research"[3] as applied across-the-board to all research, regardless of funding. Those institutions therefore have calibrated their disclosure and conflict management processes to these thresholds. In the absence of consistent federal regulations on this point, and with FDA and PHS standards in conflict, using the lower PHS threshold appears to NHRPAC as reasonable and prudent, and NHRPAC suggests that the Department strongly consider this as a potential course of action in the draft guidance, as a suggestion for an appropriate institutional approach to reporting thresholds. Perhaps the most crucial feature of a general use of the PHS standards, however, is that they would be applied to all research, regardless of source of funding, in recognition that the risk of adulteration of research integrity and subjects' informed consent cannot be regarded as limited by source of research funding.[4]

In defining duties to disclose and in analyzing conflicts of interest in research, the guidance should consider some attention to dollars flowing to researchers and institutions from the research itself, and should not be limited solely to other financial arrangements between sponsors, researchers and institutions. For example, "enrollment bonuses" are compensation within the research arrangement itself, and those bonuses have aroused considerable concern. Also, compensation terms for the researcher are subject to change during the research, but new arrangements are not routinely vetted by an IRB or any conflict of interest committee. Institutions and their IRBs are often ignorant of the contractual and financial arrangements between researchers and sponsors. The goal here should be to assure that in the process of research, investigators and institutions receive compensation only within the broad parameters of "fair market value" of services rendered. In some institutions, for example, research applications include statements or certifications from the PI and/or responsible institutional officials that the compensation received from the sponsor is commensurate with the fair market value of services provided, and that material changes in compensation be disclosed through the conflict of interest process. This certification process can act as a "tollgate" or procedural caution for PIs and institutions, requiring deliberation about the exact terms of the proposed compensation.

Conflict of interest analysis should take account of, and contain "compelling and necessary" exceptions for, situations in which physicians who treat unusual conditions invent new devices or other interventions, and yet have significant financial interests in those devices. In these cases, guidance should not discourage these physicians from inventing new devices and developing new interventions and therapies, and should not prohibit these physicians from acting

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[3] 42 C.F.R. §50.604(c)(1).

[4] Ultimately, conflicts of interest financial thresholds and disclosure standards should be harmonized between the FDA, NIH and NSF. These harmonized standards could be applied to all privately funded medical research, so that all clinical trials are subject to the same standards of disclosure and analysis. These steps would require regulatory changes, and go far beyond the "guidance" offered in the current Departmental draft.

as clinical investigators, particularly in the initial stages of investigation, since they may be in the best position to undertake critical research with a high assurance of safety for research subjects. Methods should be developed to assess and monitor conflicts of interest in these situations, and to protect patients, while not preventing essential clinical research. NHRPAC would encourage the Department to seek input on this issue from provider groups, such as the American College of Surgeons, and from cardiac surgery and orthopedic surgery professional groups.

Although at the present time, the *Draft Interim Guidance* and regulations governing researchers speak only with regard to financial conflicts of interest, in fact there are many other kinds of conflicts of interest that may provide incentives for researchers to adulterate or misinterpret data, such as the desire for fame, prestige and academic advancement. These conflicts are extraordinarily difficult to assess and measure, and to prevent. NHRPAC suggests that as guidance is developed on conflicts of interest, the possibility be entertained that non-financial interests could also lead to conflicts of interest, and that in compelling circumstances, those non-financial interests would also be considered in a conflicts of interest process.

The Financial Disclosure Process:
Conflict of Interest Committees and Designated Officials

The draft guidance appears somewhat confused on the issue of an appropriate process by which financial disclosures may be made, and those disclosures considered in a conflicts of interest analysis. NHRPAC spent much time deliberating on the practical issue of how a financial disclosure process, with its analysis of possible conflicts of interest, might work most easily in most institutional settings.

Although the consensus of NHRPAC members has been that the IRB should have ultimate plenary authority to examine potential conflicts of interest and to approve or disapprove research, all stemming from the IRB's overarching role in protecting human subjects, there has also been a profound doubt that IRBs have the expertise or staff support that would allow them to undertake insightful analysis of financial interests and conflicts of interest. For this reason, it would seem unwise to rest on IRBs the responsibility for collecting financial information and then analyzing that information to identify and suggest remedies for conflicts of interest. In most institutions (including, for example, in federal employment), there are existing conflicts of interest processes that do not in any way depend on IRBs and that are, in fact, much broader in their scope than research activities, covering, for example, purchasing, outside employment, outside activities, and investments and family interests in potential vendors of goods and services. To accomplish these purposes, most hospitals of moderate or large size have designated personnel, in human resources departments or elsewhere within the entity, who bear

the responsibility of collecting this information from employees and professional staff at periodic intervals, and then analyzing that information and taking appropriate actions.

For the draft guidance's approach to disclosures of financial interests related to research, NHRPAC would suggest that the process be conceived as a necessary adjunct of the regular IRB approval process. Just as IRBs may have adjunct bodies reporting to or assisting them, such as biosafety committees, radiation committees, finance office staff (to advise on costs to patients enrolled in research), and/or "privacy boards" (as outlined in the HIPAA regulations),[5] so too an IRB could appropriately avail itself of a conflict of interest committee or one or more administrators charged with performing the necessary duties of collecting and analyzing information related to financial disclosures. The conflict of interest entity (referred to herein as the "COI committee," even if not a committee in form but simply an institutional official or group of officials) would digest this information for the IRB, and make a formal report to the IRB regarding conflicts of interest, if any, identified in its review of financial disclosures related to the research application. The COI committee would also make recommendations to the IRB as to methods by which conflicts might be appropriately managed. The report from the COI committee would, in this scheme, be regarded as a necessary part of the research application *before* that application could be forwarded to and considered by the IRB. The IRB, holding ultimate authority over approval of research, could accept, modify, or reject the COI committee's suggestions in this regard, based on its own deliberations and on any submissions from the researchers or institution. If, on the other hand, a COI committee had come to a conclusion that the research project was so potentially corrupted by financial interests that it should not go forward, presumably an IRB could ignore that recommendation, but would do so only under compelling circumstances.

A diagram that attempts to illustrate one version of this process is attached hereto as Exhibit A.

NHRPAC was mindful in its deliberations that for independently-conducted research, such as research funded through private sponsors and occurring in physicians' offices not tied to hospitals or other institutions (*e.g.*, outpatient clinical trials conducted by independent practitioners), there is a profound need for guidance, and ultimately for some sort of regulation, on this issue. Although "freestanding" IRBs are available, little is known about any

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[5] Another related example would be a Data Safety Monitoring Board (DSMB). DSMBs are commonly used in multi-center clinical trials, and are composed of experts who have no personal connection to the trials, but whose expertise extends to the clinical conditions and/or experimental agents or methodologies being studied. DSMBs are created and used by research sponsors, but their reports, distilling and interpreting multiple significant adverse events reports, are often provided to IRBs either by the sponsors or by investigators, and allow the IRBs meaningful access to expert advice on the meaning of adverse events reports.

"freestanding" conflicts of interest committees, if any exist at all. For these independent clinical researchers, the IRBs that approve and oversee their research could be charged with a conflicts of interest function as well, either directly (if IRB members are competent to do so), or through affiliation with a COI committee or process in place at another entity.

"Institutional" Financial Relationships and Conflict of Interest

A new category of troubling financial relationships in research that has emerged from recent cases of alleged research misconduct relates to hospitals, clinics and other entities that "host" research, when those entities themselves possess investments or financial interests in the products being tested, or in the companies that own those products. The risk here is that IRB members may often include departments chairs, deans, and mid- and high-level administrators from the entity who may well understand the value of these investments to the institution, and their judgments on research approval and oversight could be altered by countervailing concerns for patent value, stock price, or related financial interests. This countervailing interest may be as attenuated (and noble) as the desire to protect the overall fiscal health of the entity, or as narrow and parochial (and disturbing) as seeking to guarantee personal end-of-year bonuses by preventing erosion of the value of intellectual property related to ongoing research studies.

There are no specific federal or (apparently) state law rules regarding financial thresholds for conflicts of interest of IRB members, and there are no such guidelines at all respecting institutional interests. For IRB members, the common practice is to require recusal of those members who have any financial interest or professional role in the research being considered. In regard to institutional conflicts of interest, the Department's draft guidance is quite specific in its suggestions on safeguarding human subjects safety. Although NHRPAC takes no specific position on the specific measures suggested in the draft guidance document, NHRPAC fully supports the Department's efforts to identify and define institutional financial interests and relationships that may present conflicts of interest and to suggest methods in which conflicts could be managed appropriately. Further, NHRPAC supports increased attention to non-affiliated IRB membership as one method of guarding against these conflicts and providing independent voices on the IRB. Finally on this issue, consistent with the conflict of interest process set forth above, NHRPAC suggests that institutional financial interests could also be disclosed to an appropriately constituted COI committee, and that the COI committee could make recommendations to the IRB on managing any institutional interests that rise to the level of a troubling financial relationship or an actual conflict of interest.

Disclosing Relevant Financial Relationships and Conflicts of Interest to Research Subjects

One of the most difficult issues in establishing a conflicts of interest process is the extent to which troubling financial relationships or possible conflicts, once identified, must be disclosed to research subjects, or potential subjects, in the informed consent process. The NHRPAC Working Group spent a great deal of time considering the various aspects of this issue, and reviewed some scholarly literature on disclosure of physician and institutional remuneration to patients. (That literature, however, deals primarily with disclosure to patients of incentives for treatment under managed care contracts.) It was pointed out that under existing standard legal and ethical analysis, not all risks are disclosed in the informed consent process, but only "significant" risks; the corollary would be that if a troubling financial relationship or conflict of interest exists, it should be disclosed only if the risk that flows from it cannot be eliminated or managed and thus reduced below the level of a "significant" risk to research subjects. NHRPAC's general sense has been that research subjects should be informed of "real" problems relating to relevant financial relationships and conflicts of interest, but should not be burdened with information about problems that are arcane and speculative. At the same time, however, due to a pressing need to bolster public confidence in the research enterprise, the majority of NHRPAC has thought that information regarding a troubling financial relationship or possible conflict of interest, once identified in the conflict of interest process, should be, in principle, available to research subjects.

How to tell patients in a meaningful and understandable way about these relevant financial relationships and conflicts, and about potential risks flowing from them, is a largely undefined process with no clear precedents. A very real risk here is that if presented with confusing, chaotic, and detailed but undigested information about investments and compensation and money flows, patients could be utterly confused, and their ability to make reasoned choices impaired rather than assisted. These issues merit a great deal of attention in the months to come, as the conflicts of interest process is refined in guidance and regulations. It is on this issue, for example, that the various professional associations could be enormously helpful in describing methods by which research subjects and potential subjects might appropriately be informed when troubling relationships or actual conflicts do exist, either at the researcher or the institutional level.

In the absence of clear precedent, however, but faced with a pressing need to provide some practical advice to IRBs, NHRPAC would advise that in a research protocol in which a possible conflict of interest has been identified in the financial disclosure process, subjects could be advised in the informed consent form in a generic way of the disclosure process, the identification of a possible conflict in the study, the fact that steps have been taken to manage the

research coordinator. This initial disclosure, however, would not contain specific mention of where the possible conflict resides or of actual financial interests held. A form of disclosure could include the following:

> Mercy Hospital maintains a financial disclosure process, by which people who conduct research and Mercy itself must disclose any significant financial investments (for example, stock shares or patent holdings) that are related to the products being tested in research. This sort of information about the study that you are considering joining was disclosed to an internal Mercy committee, which directed that steps be taken in this research study to make sure that these investments of either Mercy or the researchers do not influence the way in which you will be treated or the way this research study will be conducted. If you would like more information about the process at Mercy for disclosure of these interests and their management, or about the actual investments that are present in this study, please ask the researchers or the research coordinator, and they will assist you.

Such information in the informed consent form would serve to inform potential research subjects of the process and of the existence of significant and relevant financial interests, and subjects who are concerned about these issues would be invited, if interested, to seek more detailed information. The researchers would, of course, be under an obligation to respond accurately to subjects who ask for this additional information regarding an institution's or IRB's disclosure and conflict management *procedures* (with thresholds) and/or regarding the actual financial interests involved in the study and the ways in which those possible conflicts are being managed.

A minority on NHRPAC preferred that the actual relevant financial relationships be revealed in the informed consent process in order to provide complete transparency to research subjects. A majority, however, declined that approach, for several reasons. First, such an approach could well result in informed consent forms being made even more complicated than they are already, which was regarded as promoting confusion among subjects rather than comprehension. Second, under the scheme proposed by NHRPAC, institutions and researchers would be required actively to disclose and evaluate financial relationships in *all* research activities, regardless of source of funding, and to manage all possible conflicts or troubling financial relationships identified; and, in fact, research should not, in NHRPAC's proposed and

management strategies. Therefore, under NHRPAC's approach, disclosure of troubling financial relationships or actual conflicts to research subjects is not the preferred methodology for protecting subjects, but is an adjunct method for allowing subjects to have access to information that some may find relevant to their choices to participate in research. Finally, a NHRPAC majority felt that simply revealing researchers' personal and private financial information in widely circulated and easily available informed consent forms is also not respectful of researchers' own privacy; and the risk of abuse of such personal information could act ultimately as a disincentive for physicians and others to act as investigators.

In summary, a majority of NHRPAC preferred this approach of financial disclosure, conflicts analysis, conflicts management, "generic" disclosure, and ready availability to subjects of more specific information upon their request, as sufficiently informative to research subjects, with near-complete transparency as requested by subjects, and as appropriately demanding on researchers, institutions and IRBs to participate in a meaningful financial disclosure and conflicts of interest process. In other words, in this process, institutional and researcher disclosure and management of conflicts precedes research approval; and mere disclosure to research subjects is not substituted for the IRB, institutional and researcher duty to identify and manage possible conflicts according their established processes.

Education and Compliance

Policies respecting disclosure, conflicts of interest management, and informed consent are meaningless in any institution unless, after those policies have been adopted, they are enforced. Therefore, NHRPAC would advise the Department to include in the draft guidance an injunction that institutions "should" take steps to audit and monitor compliance with their own institutional policies and procedures on these issues, and "should" develop and enforce disciplinary standards for persons and entities that offend those policies and procedures. Further, a presumption of adoption of institutional guidelines is that researchers and other related staff and administrators be given adequate education about policies, procedures, and laws and regulations respecting financial disclosure and conflicts of interest to enable them to comply.

Conclusion

NHRPAC appreciates the opportunity to provide these comments on the Department's *Draft Interim Guidance*, and offers the Department and OHRP its full support as the Department proceeds to finalize that document.